IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL, SRL, and ORTHO-MCNEIL, INC.,	)	
Plaintiffs,	)	C.A. No. 07-255 (JJF) (CONSOLIDATED)
v.	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Defendants.	)	

AMENDED COMPLAINT

Plaintiffs Purdue Pharma Products L.P., Napp Pharmaceuticals Group Ltd., Biovail Laboratories International, SRL, and Ortho-McNeil, Inc., for their Amended Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

3. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PARTIES

4. Plaintiff Purdue Pharma Products L.P. ("Purdue") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One

Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue is an owner by assignment of the patents in suit identified in paragraphs 10 and 11 below.

5. Plaintiff Napp Pharmaceutical Group Ltd. ("Napp") is a private limited company organized and existing under the laws of the United Kingdom, having a place of business at Cambridge Science Park, Milton Road, Cambridge, CB4 0GW. Napp is an owner by assignment of the patents in suit identified in paragraphs 10 and 11 below.

6. Plaintiff Biovail Laboratories International, SRL ("Biovail") is a corporation organized and existing under the laws of Barbados, having a place of business in Carolina, Puerto Rico. Biovail is the holder of New Drug Application ("NDA") No. 21-692 and manufactures the controlled-release tramadol hydrochloride pain relief medication Ultram® ER.

7. Plaintiff Ortho-McNeil, Inc. ("Ortho-McNeil") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 1000 Route 202 South, Raritan, New Jersey 08869. Ortho-McNeil is a licensee of the '887 patent in suit identified in paragraph 10 below, and markets and distributes Ultram® ER in the United States.

8. Upon information and belief, defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at One Ram Ridge Road, Spring Valley, New York 10977.

9. Upon information and belief, defendant Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Upon information and belief, Par Pharmaceutical Companies, Inc. is the parent corporation of Par Pharmaceutical, Inc., and Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc.

THE PATENTS IN SUIT

10. Purdue and Napp are the lawful owners of all right, title and interest in and to the following United States patent, including all right to sue and to recover for past infringement thereof, which patent is listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering Ultram® ER:

United States Patent No. 6,254,887, entitled "CONTROLLED RELEASE TRAMADOL" ("the '887 patent"), a copy of which is attached hereto as Exhibit A, which was duly and legally issued on July 3, 2001, naming Ronald Brown Miller, Stuart Thomas Leslie, Sandra Therese Antoinette Malkowska, Kevin John Smith, Walter Wimmer, Horst Winkler, Udo Hahn, and Derek Allan Prater as the inventors.

11. Purdue and Napp are also the lawful owners of all right, title and interest in and to the following United States patent, including all right to sue and to recover for past infringement thereof:

United States Patent No. 7,074,430, entitled "CONTROLLED RELEASE TRAMADOL TRAMADOL [sic] FORMULATION" ("the '430 patent"), a copy of which is attached hereto as Exhibit B, which was duly and legally issued on July 11, 2006, naming Ronald Brown Miller, Sandra Therese Antoinette Malkowska, Walter Wimmer, Udo Hahn, Stuart Thomas Leslie, Kevin John Smith, Horst Winkler, and Derek Allan Prater as the inventors.

PAR'S ANDA

12. Upon information and belief, Par's Abbreviated New Drug Application ("ANDA"), submitted to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeks approval to engage in the commercial manufacture, use, and sale of

Tramadol Hydrochloride Extended Release Tablets, 100 mg, 200 mg, and 300 mg ("Par's Tablets"), a generic version of Biovail's Ultram® ER, before the expiration of the '887 patent.

13. Upon information and belief, Par's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '887 patent, listed in the FDA's Orange Book as a patent covering the drug Ultram® ER, is invalid and/or will not be infringed by the commercial manufacture, use or sale of Par's Tablets.

14. In a letter dated March 27, 2007 addressed to Biovail and Euroceltique, S.A. (listed as the assignee on the face of the '887 patent and an entity associated with Purdue and Napp), Par provided "notice" with respect to its 200 mg Tablets and the '887 patent under 21 U.S.C. § 355(j)(2)(B)(ii) ("Par's 1st notice").

15. On May 9, 2007, within the 45-day period provided by statute, Plaintiffs filed a complaint in this Court for patent infringement with respect to Par's 200 mg Tablets. This complaint received Civil Action No. 07-255-JJF.

16. In a letter dated May 21, 2007 addressed to Biovail, Napp, and Purdue, Par provided "notice" with respect to its 100 mg and 200 mg Tablets and the '887 patent under 21 U.S.C. § 355(j)(2)(B)(ii) ("Par's 2nd notice").

17. On June 28, 2007, within the 45-day period provided by statute, Plaintiffs filed a complaint in this Court for patent infringement with respect to Par's 100 and 200 mg Tablets. This complaint received Civil Action No. 07-414-JJF.

18. In a letter dated September 24, 2007 addressed to Biovail, Napp, and Purdue, Par provided "notice" with respect to its 300 mg Tablets and the '887 patent under 21 U.S.C. § 355(j)(2)(B)(ii) ("Par's 3rd notice").

19. On October 24, 2007, within the 45-day period provided by statute, Plaintiffs filed a complaint in this Court for patent infringement with respect to Par's 300 mg Tablets. This complaint received Civil Action No. 07-666-JJF.

20. Par's 1st, 2nd, and 3rd notices do not provide any valid basis for concluding that the '887 patent is invalid and/or not infringed by its Tablets.

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT UNDER 35 U.S.C. § 271(e)(2)

21. Par's submission of its ANDA was an act of infringement of the '887 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

22. Upon information and belief, the composition of Par's Tablets is covered by one or more claims of the '887 patent.

23. Upon information and belief, Par's commercial manufacture, use, sale, and/or offer for sale of its Tablets would infringe, contribute to the infringement of, and induce the infringement of one or more claims of the '887 patent.

24. Upon information and belief, Par has been aware of the existence of the '887 patent, and has no reasonable basis for believing that its Tablets will not infringe the '887 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

25. The acts of infringement by Par set forth above will cause plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

SECOND CLAIM FOR RELIEF: DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

26. Upon information and belief, once the FDA grants tentative approval of Par's ANDA, Par will undertake substantial activities directed toward engaging in infringement, contributory infringement, and active inducement of infringement of the '430 patent by making,

using and undertaking substantial preparations for offering to sell, without authority from plaintiffs, its Tablets, whose compositions are covered by one or more claims of the '430 patent.

27. Upon information and belief, Par has been aware of the existence of the '430 patent but, once the FDA grants tentative approval of Par's ANDA, Par will nevertheless engage in substantial activities directed toward infringing, contributorily infringing, and actively inducing the infringement of the '430 patent. These activities will be in total disregard for plaintiffs' lawful rights under the '430 patent, thus rendering this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

28. Once the FDA grants tentative approval of Par's ANDA, these substantial activities engaged in by Par directed toward infringement, contributory infringement, and active inducement of infringement as set forth above demonstrate the existence of an actual and justiciable controversy, and, if allowed to continue and progress, will inevitably constitute infringement, contributory infringement, and active inducement of infringement of the '430 patent, will cause plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless preliminarily and permanently enjoined by this Court.

WHEREFORE, plaintiffs pray for judgment:

On the First Claim for Relief:

A. Adjudging that Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. have infringed the '887 patent, and that the commercial sale, offer for sale, and/or manufacture of Par's Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '887 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Par's ANDA No. 78-783, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '887 patent;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc., their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '887 patent;

D. Declaring this an exceptional case and awarding plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding plaintiffs such other and further relief as this Court may deem just and proper.

On the Second Claim for Relief:

F. Declaring that the manufacture, use, and substantial preparations for offering for sale of Par's Tablets, if allowed to continue and progress, will constitute infringement, contributory infringement and active inducement of infringement of the '430 patent;

G. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. § 283 and Rule 65, Fed. R. Civ. P., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc., their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '430 patent;

H. Declaring this an exceptional case and awarding plaintiffs their attorneys' fees, as provided by 35 U.S.C. § 285; and

I. Awarding plaintiffs such other and further relief as this Court may deem just and proper.

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